

June 7, 2006

MEMORANDUM TO: J. E. Dyer, Director
Office of Nuclear Reactor Regulation

THRU: Michael E. Mayfield, Director
Division of Engineering
Office of Nuclear Reactor Regulation

FROM: Richard P. McIntyre, Senior Reactor Engineer **/RA/**
Quality and Vendor Branch A
Division of Engineering
Office of Nuclear Reactor Regulation

SUBJECT: TRIP REPORT BY THE QUALITY AND VENDOR BRANCH
(EQVA/EQVB) STAFF OF THE NUCLEAR PROCUREMENT ISSUES
COMMITTEE JOINT UTILITY AUDIT AT MITSUBISHI HEAVY
INDUSTRIES (MHI) MANUFACTURING FACILITIES

On May 15-19, 2006, Richard McIntyre and Greg Galletti of the Division of Engineering (DE) observed the performance of a Nuclear Procurement Issues Committee (NUPIC) joint utility audit conducted at the Mitsubishi Heavy Industries facilities (MHI) in Kobe, Japan. The purpose of the observation was to assess the NUPIC audit process used for suppliers of components to the nuclear industry. The DE staff also provided clarification on issues related to the U.S. Nuclear Regulatory Commission (NRC) regulations, including input regarding inadequacies in the 10 CFR Part 21, "Reporting of Defects and Noncompliance" program for MHI facilities. Enclosed is the trip report of the NRC staff's observations and a list of the persons contacted during the trip. The content of this report may be of interest to the Commission and it is recommended that it be forwarded to the Commission.

Enclosure:
As stated

Contact: Richard P. McIntyre, NRR/DE
301-415-3215

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DATE	6/6/2006	6/6/2006	6/6/2006	6/7/2006	

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NRC FOREIGN TRIP REPORT

Subject

This trip report documents observations by members of the Nuclear Regulatory Commission (NRC) Office of Nuclear Reactor Regulation (NRR), Division of Engineering (DE) of a Southern California Edison led Nuclear Procurement Issues Committee (NUPIC) joint utility audit conducted on May 15-19, 2006, at Mitsubishi Heavy Industries facilities, in Kobe, Japan. In addition, the report documents observations of their 10 CFR Part 21 process.

Dates of Travel and Countries/Organization Visited

May 15-19, 2006, Mitsubishi Heavy Industries, in Kobe, Japan.

Author, Title and Agency Affiliation

Richard P. McIntyre, Team Leader
Quality and Vendor Branch A (EQVA)
Division of Engineering
Office of Nuclear Reactor Regulation

Sensitivity

There were no documents removed from the facility during the conduct of the audit. This document is available to the public (ADAMS Accession No.: ML061570442).

Background/Purpose

This trip report documents the staff's assessment of a Nuclear Procurement Issues Committee (NUPIC) joint utility audit conducted at Mitsubishi Heavy Industries (MHI), in Kobe, Japan, on May 15-19, 2006. The MHI facility manufactures safety-related and ASME code items, components, and performs engineering services for U.S. nuclear utilities in accordance with ASME Section III and/or Appendix B to 10 CFR Part 50 requirements. The nine-person audit team included representatives from Southern California Edison (SCE), South Texas Project (STP), and Omaha Public Power District (OPPD).

At the request of both SCE and NUPIC, representatives of the NRR Division of Engineering (DE), Quality and Vendor Branches A and B (EQVA and EQVB) observed the NUPIC joint utility audit at MHI. Both SCE and the NUPIC Chairman requested NRC participation to help foster a more comprehensive audit and to allow MHI to experience first hand input from the U.S. nuclear regulator.

NRC/NUPIC Interface

NUPIC was formed in 1989, by a partnership involving all domestic and several international nuclear utilities. The NUPIC program evaluates suppliers furnishing safety-related components and services and commercial grade items to nuclear utilities.

Enclosure

The purpose of the Quality and Vendor Branch observation of this SCE led NUPIC joint utility audit was to ensure the audit process remains an acceptable alternative to the NRC vendor inspection/audit program. The NRC staff continues to rely on the effectiveness of the NUPIC joint utility audit process for evaluating the implementation of quality assurance (QA) programs of suppliers to the nuclear industry.

Abstract: Summary of Pertinent Points/Issues

Oversight of the NUPIC audit process is viewed by the staff as particularly relevant for two reasons: (1) Licensees and the NRC continue to rely on NUPIC for oversight of current suppliers to the nuclear industry and; (2) NRC may rely on NUPIC for oversight of suppliers during construction of future generation reactors. The staff anticipates that new suppliers, both domestic and international, will enter the nuclear supplier business due to an expanded nuclear marketplace. The staff has had ongoing discussions with the NUPIC Steering Committee on the role NUPIC may take in evaluating these new suppliers during new plant construction. The staff will need to evaluate NUPIC's capabilities and plans for oversight of the potential expanding supplier base for the next generation of nuclear plants.

Discussion

The NUPIC audit scope was to determine the acceptability and verify the effective implementation of the MHI quality assurance program in accordance with the requirements of Appendix B to 10 CFR Part 50. The NUPIC audit team utilized the NUPIC audit checklist that is essentially divided into the 18 criteria of Appendix B, for this audit. This checklist was supplemented by ASME, ANSI and other recognized consensus standards relevant to the supplier being audited. The NUPIC audit checklist can be downloaded from the NUPIC web site (www.nupic.com).

The performance-based NUPIC checklist was used by the team to assess the adequacy and effectiveness of the MHI quality assurance program. The audit checklist delineated the activities to be examined within each section and how to utilize the referenced data sheets to record the objective evidence reviewed for each section. The review included an analysis of MHI's order entry process, an examination of design, software QA, procurement and material controls associated with specific utility orders, and field (shop) observations of fabrication, assembly, special processes (such as welding and non-destructive examination, NDE), tests, and inspection activities. Also, the NUPIC audit team completed a review of calibration of measuring and test equipment, handling, storage, and shipping activities.

The staff observed all aspects of the NUPIC Team's conduct of the audit at MHI. This began with the audit team meeting conducted the day before the audit commenced, to go over details of the audit and all audit expectations. For observance of the conduct of the audit, the team divided the audit checklist review areas between the two NRC staff members. The staff then observed performance of the auditors as they conducted a performance based review of a specific audit checklist section. The staff observed how documents were selected for review and the adequacy of the review, interviews conducted of MHI technical personnel, and observed on-going work and testing activities in MHI's manufacturing facility. These included observation of both fabrication activities and several calibration and NDE activities including ultrasonic inspection of a tube support plate, and magnetic particle inspection of selected steam

generator components. The staff observed the daily meetings the audit team conducted internally, the daily debrief with MHI personnel, and the formal exit meeting with MHI management. NRC staff also reviewed the NUPIC audit findings and observations that were presented to MHI.

The NUPIC audit team included nine auditors. The checklist sections were divided among the audit team members, with one of the five SCE auditors performing a managerial function as the audit team leader. Three representatives from STP and one representative from OPPD completed the audit team. In addition to the generic audit checklist, other items that the audit focused on were: design control; software verification and validation; nonconformance and corrective action process; calibration of measuring and test equipment; welding activities; and nondestructive examination (NDE).

The NUPIC audit team reviewed the MHI Quality Assurance Manual and other lower tier implementing documents such as procedures and work instructions. The NUPIC audit was performed by reviewing the requirements of the QA program and supporting implementing procedures, and evaluating the resulting documentation associated with the activities that had been performed. Additionally, the NUPIC team discussed the activities with MHI personnel, and observed ongoing work and inspection activities associated with the fabrication shop.

All of the NUPIC audit team members were observed by the staff in part or in whole on their portion of the audit conducted. The NRC staff determined that the NUPIC audit team adequately implemented the requirements of the NUPIC checklist. The NUPIC audit team performed a sound, thorough, performance-based review of the audited areas.

The NUPIC audit team identified four preliminary findings and recommendations with the implementation of the MHI quality program. These preliminary findings and recommendations were discussed in detail with MHI management during the final daily debrief and at the formal exit meeting. The findings and recommendations represented the following program areas: design control procedural noncompliance, report of nonconforming materials, parts, or components and corrective action, internal/external audit process, documentation of periodic reviews, and instructions procedures and drawings.

The staff reviewed implementation of 10 CFR Part 21, "Reporting of Defects and Noncompliance," at the MHI facilities. The staff held several discussions with MHI personnel concerning their responsibilities under Part 21 and conducted in-depth discussions on the proper implementation of Part 21 with MHI management and personnel. The staff also provided input for the NUPIC audit finding regarding inadequacies in the 10 CFR Part 21 program at MHI plant facilities. These issues included failure to have an appropriate procedure to evaluate a potential Part 21 reportable condition and failure to adequately post per the requirements of Part 21.

Finally, the staff emphasized to MHI management at the formal exit meeting the need to adequately implement all the requirements of 10 CFR Part 21 .

Conclusions

The NUPIC audit team leader conducted effective daily briefings with the audit team and MHI on the issues and potential findings. These daily briefings enhanced the audit team's understanding of issues and findings and provided an effective feedback mechanism from experienced audit team members on the significance of individual team findings. The staff suggested that it might have been more effective for the audit team leader to allow the individual audit team members to discuss their issues and findings with MHI's management and audit counterparts at the daily debrief. The auditors supported their findings with comprehensive objective evidence and went to sufficient depth in their respective areas of focus.

Overall, the staff concluded, based on the review of the audit areas covered, that the NUPIC audit process was effectively implemented by the audit team and resulted in sound performance based findings for failure to adequately implement QA program requirements.

Pending Actions/Planned Next Steps for NRC

This NRC assessment at MHI was one of at least two planned for 2006. The assessment process was outlined to NUPIC members at the March 2004 NUPIC meeting. Since that meeting, the NRC has planned and conducted at least two assessments a year of NUPIC joint utility audits or commercial grade surveys to ensure the adequacy of the NUPIC joint utility audit process.

Points for Commission Consideration/Items of Interest

Inadequacies with the implementation of the 10 CFR Part 21 regulation were identified during this NUPIC audit observation and at other audit observations of foreign suppliers who are currently manufacturing components for the US nuclear industry. Similar 10 CFR Part 21 process and implementation issues have also been identified at recent inspections of domestic suppliers.

List of Persons Contacted

U.S. NRC

Position

Richard P. McIntyre
Greg S. Galletti

Team Leader, Senior Reactor Engineer
Senior Operations Engineer

NUPIC

Stu Rushing
Robert McWey
Ernest Torres
Manny Enriquez
David Holler

Audit Team Leader, Southern California Edison (SCE)
Manager, Project Oversight, SCE
Project Manager, RSG/RVH Oversight, SCE
Senior Engineer, SCE
Audit Team Member, SCE

Tim Walker	Manager, Vendor Oversight, South Texas Project (STP)
Jim Adkins	Audit Team Member, STP
Steve Thomas	Technical Specialist, STP
Bernie Saucier	Technical Specialist, Omaha Public Power District, OPPD
H. Gunther Domschke	Quality Resident Representative - SCE and OPPD

Mitsubishi Heavy Industries (MHI)

Akira Sawa	Senior Vice President - General Manager
Shigero Masamori	Deputy General Manager
Takuya Kitera	Manager, Quality Assurance Department
Kenichi Sonoda	Manager, Special Projects
Ikuo Otake	Manager, Overseas Projects Team, Nuclear Quality Assurance section
Kyoji Kano	Engineering Manager, Quality Assurance Department,
Kyoichi Aizawa	Engineering Manager, Quality Assurance Department
Masayoshi Suzuki	Engineering Manager, Quality Assurance Department
Kensaku Yajima	Export Marketing Section, MHI
Yoshinori Takata	Project Manager, Overseas Projects
Kensaku Yajima	Export Marketing Section
N. Yonaha	Interpreter